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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,643	08/21/2003	Adrian Liem	4-32682A	8789

1095 7590 12/28/2006

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
FORD, VANESSA L	
ART UNIT	**PAPER NUMBER**
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,643	LIEM ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *8/16/06* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to Applicant's amendment and response filed October 4, 2006. Claim 21 has been amended. It should be noted that an Interview Summary of the telephonic interview held August 16, 2006 is enclosed.

Rejections Withdrawn

2. In view of Applicant's amendment and response the following rejections are withdrawn.

a) the rejection of claims 21-22 under 35 U.S.C. 112 first paragraph, pages 2-3, paragraph 3 of the previous Office action.

b) the rejection of claims 21-22 under 35 U.S.C. 112 second paragraph, page 3, paragraph 4 of the previous Office action.

c) the rejection of claims 21-22 under 35 U.S.C. 103(a), pages 4-6, paragraph 5 of the previous Office action.

d) the rejection of claims 21-22 under 35 U.S.C. 103(a), pages 6-9, paragraph 6 of the previous Office action.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 21-22 are rejected under 35 U.S.C. 103(a) as unpatentable over Clark et al *(Aust. Vet J. 1986, Apr; 63(4):107-10)* in view of Abe et al *(Infection and Immunity, May 1976, p. 1473-1478).*

Claims 21-22 are drawn to a method of preventing footrot and liver abscesses in bovines caused by infection with *Fusobacterium necrophorum* bacteria, wherein said method is comprised of:

(a) growing an isolate of *Fusobacterium necrophorum* bacteria, taken from a bovine species, for successive generations in a suitable growth medium for a period of time equal to between 10 hours and 18 hours to form an *Fusobacterium necrophorum* bacteria whole cell culture, with said bacteria culture having a bacterial count population equal to at least 1 x 10^5 CFU/ml, and wherein said *Fusobacterium necrophorum* whole cell culture contains the growth medium in which said *Fusobacterium necrophorum* is grown:

(b) inactivating said *Fusobacterium necrophorum* culture by contacting said culture with formaldehyde;

(c) forming a vaccine by combining said inactivated *Fusobacterium necrophorum* culture with an amount of diluent; and

(d) administering at least one dosage of said vaccine subcutaneously to a bovine subject with said dosage of about 1 ml to about 2 ml.

Clark et al teach that *Fusobacterium necrophorum* is effective in preventing interdigital necrobacillosis (footrot) (see the Abstract). Clark et al teach that vaccine compositions contained whole cultures, of killed cells formulated in a mineral oil adjuvant (page 107-108). Clark et al teach that vaccine compositions comprising culture supernatants provided the most protection against footrot in cattle (see the Abstract and page 109). Clark et al teach that *Fusobacterium necrophorum* can be cultured on suitable medium for a period of time up to 18 hours (page 107). Therefore, the prior art teaches the claim limitation "...successive generations in a suitable growth medium for a period of time equal to between 10 hours and 18 hours to form an *Fusobacterium necrophorum* bacteria whole cell culture, with said bacteria culture" is taught by the prior art. Clark et al teach that a degree of protection against interdigital necrobacillosis was obtained in group 1 and 3 that were given vaccines containing concentrated whole culture (page 109).

Clark et al do not specially teach that the whole cells were inactivated by using formaldehyde nor does Clark et al teach preventing liver abscesses.

Abe et al teach that members of the family *Bacteroidaceae* have been implicated in a variety of infections including liver abscesses (page 1473). Abe et al teach a mouse model in which intraperitoneal injection of bovine strain of *Fusobacterium necrophorum* results in liver abscesses (see the Abstract). Abe et al teach that liver abscesses containing bacteria from the family *Bacteroidaceae* may be associated with 100% morality when undiagnosed (page 1473). Abe et al teach that vaccine compositions comprising formalin killed *Fusobacterium necrophorum* and protected animals from subsequent challenge doses of *Fusobacterium necrophorum* (page 1473). Abe et al teach twenty-four hours post-challenge there was no detectable bacteria in the liver, lung or spleen (page 1475 and figure 3, page 1476). Abe et al teach that extended immunization with formalin killed cells was found to protect mice against F. *necrophorum* infection (see the Abstract).

It would be *prima facie* obvious at the time the invention was made to use formalin-killed vaccine compositions comprising whole-cell cultures of *Fusobacterium necrophorum* in a method of preventing footrot and liver abscesses in bovine because Clark et al has demonstrated that compositions comprising *F. necrophorum* whole cell cultures are effective in preventing footrot in cattle and Abe et al teach that vaccine compositions comprising formalin killed *Fusobacterium necrophorum* protected animals from *Fusobacterium necrophorum* infections (which included clearance of live abscesses). It would expected barring evidence to the contrary that vaccine compositions comprising formalin killed *F. necrophorum* whole cell cultures would be effective in preventing infections caused by *F. necrophorum*.

Status of Claims

4. No claims allowed.

Conclusion

5. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached at (571) 272-0787.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
December 22, 2006

NITA MINNIFIELD
PRIMARY EXAMINER